K103249

CardinalHealth

DEC 16 2010

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

NITRILE POWDER-FREE EXAMINATION GLOVES

Manufacturer:	YTY Industry (Manjung) Sdn. Bhd. Lot 1422 – 1424, Batu 10 Lekir, 32020 Sitiawan, Perak Darul Ridzuan, Malaysia
Regulatory Affairs Contact:	Tatyana Bogdan, RAC Cardinal Health, Inc. 1430 Waukegan Road McGaw Park, IL 60085
Telephone:	847-887-2325
Date Summary Prepared:	October 11, 2010
Product Trade Name:	Stretchy Nitrile Cornflower Blue Powder-Free Exam Gloves with Tested for Use with Chemotherapy Drug Labeling Claim
Common Name:	Exam Gloves
Classification Name:	Patient Examination Gloves
Device Description:	These patient examination gloves are formulated using Nitrile. They are a disposable device that is offered powder-free and non-sterile. Gloves are cornflower blue in color. Gloves are not made with natural rubber latex.

Intended Use:

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs:

	Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time in Minutes, 0.01 $\mu g/cm^2$/minute
1.	**Carmustine (BCNU) (3.3 mg/ml)**	**7.28**
2.	Cisplastin, (1.0mg/ml)	>240
3.	Cyclophosphamide (20 mg/ml)	>240
4.	Doxorubicin HCl (2.0 mg/ml)	>240
5.	Etoposide (Toposar) (20 mg/ml)	>240
6.	5-Fluorouracil (50 mg/ml)	>240
7.	Methotrexate (25 mg/ml)	>240
8.	Paclitaxel (Taxol) (6.0 mg/ml)	>240
9.	**Thiotepa (10 mg/ml)**	**2.67**

The maximum testing time is 240 minutes. Please note that the following drugs have extremely low permeation time of less than 30 minutes:

Carmustine (BCNU) (3.3 mg/ml)
Thiotepa (10 mg/ml)

Predicate Devices:

Nitrile Blue Powder-Free Examination Gloves with Tested for Use with Chemotherapy Drug Labeling Claim previously cleared under 510(k) K022765 (product code LZA);

Substantial Equivalence:

These Nitrile powder-free examination gloves are substantially equivalent to the predicate device identified in this 510(k) summary. Substantial equivalence can be established in regard to intended use, physical characteristics, design and product features. Both gloves are made with Nitrile using similar manufacturing processes. In addition, both gloves have been tested for use with chemotherapy drugs.

Performance Testing:

Test:	Result:
Primary Skin Irritation	Gloves are non-irritating.
Guinea Pig Maximization	Gloves do not display any potential for sensitization.

Dimensions	Gloves meet requirements of ASTM D6319.
Physical Characteristics ASTM	Gloves meet requirements for Nitrile examination gloves per D6319.
Freedom from Holes	Gloves meet requirements of 21 CFR 800.20 and ASTM D6319
Powder Residual	Gloves meet powder level requirements for "Powder-Free" designation per ASTM D6319 tested using ASTM standard D6124, Standard test method for residual powder on medical gloves. Results generated values below 2mg of residual powder per glove.
Chemotherapy Permeation	Gloves were tested using ASTM D6978, Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs. The maximum testing time is 240 minutes.

Clinical Data:

No clinical data is required.

Conclusion:

The Stretchy Nitrile Powder-Free Exam Gloves meet the technological characteristics of ASTM D6319 performance standard and are substantially equivalent to the predicate device identified in this 510(k) summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Cardinal Health, Incorporated
C/O Ms. Tatyana Bogdan
Responsible Third Party Official
Underwriters Laboratories, Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062

DEC 16 2010

Re: K103249
Trade/Device Name: Nitrile Cornflower Blue Powder-Free Exam Gloves tested for use with Chemotherapy Drugs Labeling Claim
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: December 10, 2010
Received: December 13, 2010

Dear Ms. Bogdan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

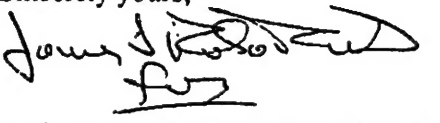
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEC 16 200

Indications for Use

510(k) Number (if known): K103249

Device Name: Nitrile Cornflower Blue Powder-Free Exam Gloves WITH TESTED for USE with Chemotherapy Drugs Labeling Claim

Indications for Use: A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

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Thiotepa (10 mg/ml)

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth D. Claire Will

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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